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K021932
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510K Summary
06-SEP-2002
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3.0 510(k) Summary

Sponsor:

Synthes (USA)
1690 Russell Road
Paoli, PA 19301
(610) 647-9700

Contact: Bonnie Smith

Device Name: Synthes 6.5 mm Cannulated Screw

Classification: The classification for Synthes 6.5 mm Cannulated Screw is Class II, as per Title 21 of the Code of Federal Regulations, Section 888.3040: "Smooth or threaded metallic bone fixation fastener".

Predicate Device: Predicate devices for the Synthes 6.5 mm Cannulated Screw are the Synthes 7.3 mm Cannulated Screw and the Alphatec 6.5 Cannulated Screw.

Device Description: Synthes 6.5 mm Cannulated Screw is a self-tapping and self-drilling screw with a cancellous thread that can be guided into a position via a guidewire. Screws are available partially or fully threaded, in thread / screw lengths of 16 mm / 30 – 200 mm, 32 mm / 45 – 200 mm and full / 20 – 200 mm. Synthes 2.8 mm guidewires in 300 and 450 mm lengths are used for precise placement in bone.

Intended Use: Synthes 6.5 mm Cannulated Screw is intended for fracture fixation of large bones and large bone fragments, such as femoral neck fractures; slipped capital femoral epiphyses; an adjunct to DHS in basilar neck fractures; tibial plateau fractures; ankle arthrodeses; pediatric femoral neck fractures; intercondylar femur fractures; SI joint disruptions; and subtalar arthrodeses.

Materials: Stainless steel and titanium alloy

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 6 2002

Synthes
Bonnie J. Smith
Senior Regulatory Affairs Associate
1690 Russell Road
Paoli, Pennsylvania 19301

Re: K021932
Trade/Device Name: Synthes 6.5 mm Cannulated Screw
Regulation Number: 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: June10, 2002
Received: June 12, 2002

Dear Ms. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

2.0 Indications for Use Statement

510(k) Number (if known): K021932

Device Name: Synthes (USA) 6.5 mm Cannulated Screw

INDICATIONS: Synthes 6.5 mm Cannulated Screw is intended for fracture fixation of large bones and large bone fragments, such as femoral neck fractures; slipped capital femoral epiphyses; an adjunct to DHS in basilar neck fractures; tibial plateau fractures; ankle arthrodeses; pediatric femoral neck fractures; intercondylar femur fractures; SI joint disruptions; and subtalar arthrodeses.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices